

Notice of Allowability	Application No.	Applicant(s)	
	09/978,309	CRUZ ET AL.	
	Examiner	Art Unit	
	Samuel W Liu	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 3-23-04.
2. ☒ The allowed claim(s) is/are 1 and 34-48.
3. ☒ The drawings filed on 15 October 2001 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|---|--|
| <ol style="list-style-type: none"> 1. <input type="checkbox"/> Notice of References Cited (PTO-892) 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) 3. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date <u>11-7-03 & 3-23-04</u> 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | <ol style="list-style-type: none"> 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date <u>4-8-04</u>. 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance 9. <input type="checkbox"/> Other _____. |
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Art Unit: 1653

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 23 March 2004 has been entered.

Note that the references cited in the IDS filed 25 February have been considered by Examiner; and applicants were requested to provide PTO-1449 form that includes said references (see the Office action mailed 24 December 2003). Here, Examiner signed the PTO-1449 for this IDS. Also, please note that Examiner has considered the references listed in the PTO-1449 form filed 7 November 2003, which form was signed and dated 15 December 2003 (see the Office action mailed 24 December 2003), and note that, here, Examiner initialed the references at "Examiner Initial" column in the PTO-1449. Further, note that the references cited in the PTO-1449 submitted by applicants on April 8, 2004 for the IDS filed 16 April 2002 have been considered.

This Office action is in response to applicants' amendments filed 23 March 2003 which amends claim 1, cancels claims 2-33, and adds claims 34-48. The amendment indicated above has been entered. The pending claims 1 and 34-48 are therefore examined in this Office action.

EXAMINER'S AMENDMENT

An Examiner's Amendment to the record appears below. Should the change and/or additions be unacceptable to Applicant, an amendment may be filed as provided by 37 C.F.R. § 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than payment of the Issue Fee.

Authorization for this Examiner's Amendment was given in a telephone interview with Mary Ann Dillahunty on April 8, 2004. Applicants agree the examiner proposed amendment to claims 1, 36, 43 and 46 (see below).

Amendments to the claims:

Art Unit: 1653

The pending claims 1, 36, 43 and 46 have been amended as follows. Please replace the previous claims with the claim shown below.

Claim 1 (*Twice amended*): After “the amino acid sequence”, change “human S3 (SEQ ID NO:74)” to “of SEQ ID NO:74”.

Claim 36 (*Amended*): After “the amino acid sequence”, change “human S3 (SEQ ID NO:74)” to “of SEQ ID NO:74”.

Claim 43 (*Amended*): After “which is”, change “adapted” to “formulated”.

Claim 46 (*Amended*): The vaccine composition of claim 45 for preventing multiple sclerosis.

The following is an **Examiner's Statement of Reasons for Allowance**:

The prior art of record does not teach or suggest the disclosed cyclosporin compound and method of treating autoimmune disease and preventing organ transplantation is subject comprising administering said cyclosporin compound. Claim 48 is drawn into a method of treating a condition comprising administering to a subject the polypeptide(s) as claimed in claims 1 or 34-39. Claims 1 and 34-47 are drawn to the allowable products. In consideration of the method claim 48, pursuant to the procedures set forth in the Official Gazette notice dated March 26, 1996 (1184 O.G. 86), are subject to being rejoined. The claims 1 and 34-48 are therefore allowable over the art of record.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled “Comments on Statement of Reasons for Allowance.”

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Samuel Wei Liu, Ph.D. whose telephone number is (571) 272-0949. The Examiner can normally be reached daily except alternate Fridays from 8:30 A.M. to 5:30 P.M. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Christopher Low, can be reached at (571) 272-0951. The official fax number for Technology Center 1600 is (703) 308-4242. Any inquiry of a general nature or relating to the

Application/Control Number: 09/978,309

Page 4

Art Unit: 1653

status of this application or proceeding should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

SWL

Samuel W. Liu, Ph.D.

April 9, 2004

Karen Cochrane Carlson PhD

KAREN COCHRANE CARLSON, PH.D.
PRIMARY EXAMINER